

Dr David A. Lepay
Office for Science and Health Coordination
Good Clinical Practice Programs (HF-34)
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857
United States of America

Vienna, 8 September 2004

Dear Dr Lepay,

Re: Docket No. 2004N-0018: Human Subject Protection; Foreign Clinical Studies
not Conducted Under an Investigational New Drug Application

As a member of the World Medical Association we strongly support and estimate the principles for international research ethics stated in the Declaration of Helsinki.

Therefore the Austrian Medical Chamber wants to express its concern about the agency's proposal to strike reference to the Declaration of Helsinki from FDA drug regulations and to advocate for withdrawing this proposal.

With best regards,

Dr Reiner Brettenthaler
President